User Guide

RCS® High Flow Touch Microbial Air Sampler

Version 7.0

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.

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1. General information

This chapter provides information of general interest regarding the instrument.

1.1.Safety information

IT IS IMPORTANT TO READ THE SAFETY INSTRUCTIONS AND THE USER GUIDE BEFORE USING THIS INSTRUMENT.

Please read the safety instructions and the user guide delivered with the instrument carefully before using the instrument and/or any accessory supplied with this product.

1.2 Operation

Personnel qualification

The microbial air sampler is a precision instrument for industrial and laboratory use. Its use should be restricted to trained, qualified and authorized personnel only.

Intended product use

The RCS® High Flow Touch is used during microbiological quality control as part of a risk-based quality assurance. The instrument is used to determine the microbial contamination of ambient air via impaction on an agar medium. For details about the application and its restrictions refer to chapter 2.2.

Operating conditions

Please refer to the safety instruction "RCS – High Flow Touch Microbial Air Sampler addendum" delivered with the instrument.

«Dual-Use» statement

The instrument is designed solely for civilian purposes. It is excluded in the scope of the European «Dual-Use» regulation.

1.3 Product Type Plate

Signifance of the icons on the type plate

RCS High Flow Touch	Indicates the instrument description
Microbial Air Sampler	Indicates the instrument type

Power input	24 Volt DC, 72 Watt
	Read the instructions before using the instrument
	Reference number (1.44194.0001)
	Individual serial number
	Identifies the manufacturer of the instrument: Millipore SAS 67120 Molsheim France, Made in India
	With this symbol the manufacturer declares conformity with the WEEE directive as described in the «Declaration of Conformity» which can be found as printout delivered with the instrument. It should not be disposed of as household waste at the end of its life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this instrument from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources. Users should either send the instrument back to the supplier or dispose it locally in accordance with the applicable local waste legislations
	With the CE symbol the manufacturer declares conformity with the relevant directives of the European Union as stated in the «Declaration of Conformity».
	With the UK Conformity Assessed (UKCA) marking the manufacturer declares conformity with the relevant directives of Great Britain as stated on the «Declaration of Conformity».
	With the EAC symbol the manufacturer declares conformity with the relevant directives of the Eurasian Trade Union as stated on the «Declaration of Conformity».
	With the RCM symbol the manufacturer declares conformity with both electrical safety and EMC requirements. Its use is controlled by a standard as stated on the «Declaration of Conformity».
	This symbol indicates that product does not contain any toxic or hazardous substances or elements above the maximum concentration value established by the Chinese standard as stated on the «Declaration of Conformity».

2 Introduction

2.1 The RCS® High Flow Touch Microbial Air Sampler

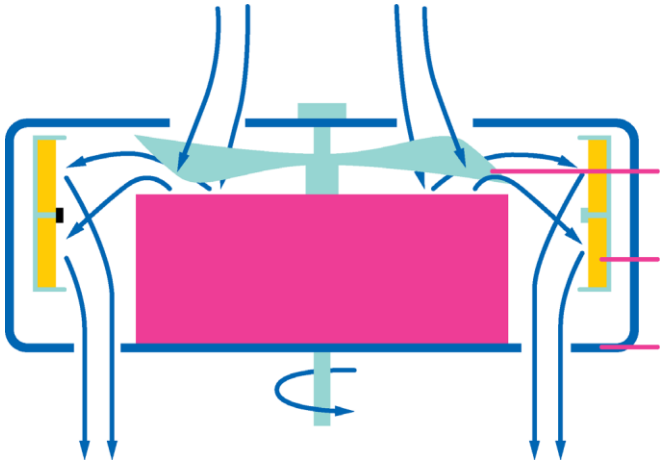
Microorganisms in the air are a potential risk for production processes of different industries and are of life-threatening risk in the health care sector. RCS® Microbial Air Samplers are designed for the inspection of the microbial quality of ambient air, the operational reliability of air conditioning systems and constructions, and for monitoring the efficiency of air treatment and disinfection measures according to guidelines for cleanroom environments (e.g. the GMP, FDA, USP, EP and ISO regulations). Together with the optional compressed gas adapter microorganisms in compressed gases can be collected.

The microbial air sampler RCS® High Flow Touch is specially designed for use in controlled production areas. It consists of an easy-to-disinfect Lexan polycarbonate housing and an autoclavable sampling head. In combination with the standardized agar strips a RCS® High Flow Microbial Air Sampler is suitable for use in Biocontamination Control.

RCS® Microbial Air Samplers are routinely used in environments where the microbial counts shall not exceed the limits given by regulations or internal quality standards.
The RCS® High Flow Touch Microbial Air Sampler allows the easy examination of high and low amounts of microorganisms in ambient air and compressed gas in the following areas:

- Pharmaceutical industry (e.g. sterile and aseptic production lines)
- Medical device industry
- Hospitals (e.g. operating theatres and intensive care units)
- Food and beverage industry
- Cosmetic industry
- Packing industry
- Other areas that require indoor or outdoor air quality monitoring

2.2 Functional Principle



The RCS® High Flow Touch Microbial Air Sampler employs the centrifugal impaction principle according to Reuter (Reuter Centrifugal Sampler, RCS®). Here, a quantitative collection of airborne microorganisms in air volumes from 1-1999 L is accomplished. The air stream enters the rotor at the front of the instrument and is set into rotation by the movements of the rotor. Microorganisms contained in the air are then separated onto the agar strip through centrifugal forces. To prevent turbulences in the air inlet channel, the air outlet passage is directed to the bottom, in parallel to the instrument. This design feature avoids recirculation of the air. Built-in electronic circuits control the speed and the running time of the motor and simultaneously monitor the battery capacity. The air flow rate is constant at approximately 100 L/min at a fixed rotor speed of 8200 rpm.

The sampling head consists of the rotor (anodized aluminum), the protection cap (stainless steel) and the air direction ring (APEC polycarbonate). The rotor, which contains the agar strip, is installed via a magnetic coupling flange allowing for easy installation and removal. For safety reasons, a stainless-steel protection cap is placed over the rotor. To ensure exact sampling volumes and to allow comparable results between rotors and instruments, each rotor is calibrated with a given instrument. Recalibration of the rotor is recommended once a year.

The RCS® High Flow Touch Microbial Air Sampler is operated by using a color touchscreen that is located in front of the carrying handle. The intuitive software contains evident icons that allow fast and direct interactions with an easy touch. The RCS® High Flow Touch Microbial Air Sampler is constructed with special attention to ergonomics. The sampler is portable and operates independently from mains using an integrated, rechargeable Lithium-ion battery. Alternatively, the instrument can be operated with a power supply. The power supply is also used to recharge the integrated battery. Further, an optional docking station is available. During battery operation the integrated software allows for continuous control of the battery charging status, and the number of remaining measurements per selected sample volume.

Factory settings include preset sampling volumes of 10, 20, 50, 100, 200, 500 and 1000 L. In addition, three individual sampling volumes from 1 to 1999 L can be programmed. Optional sampling settings include:

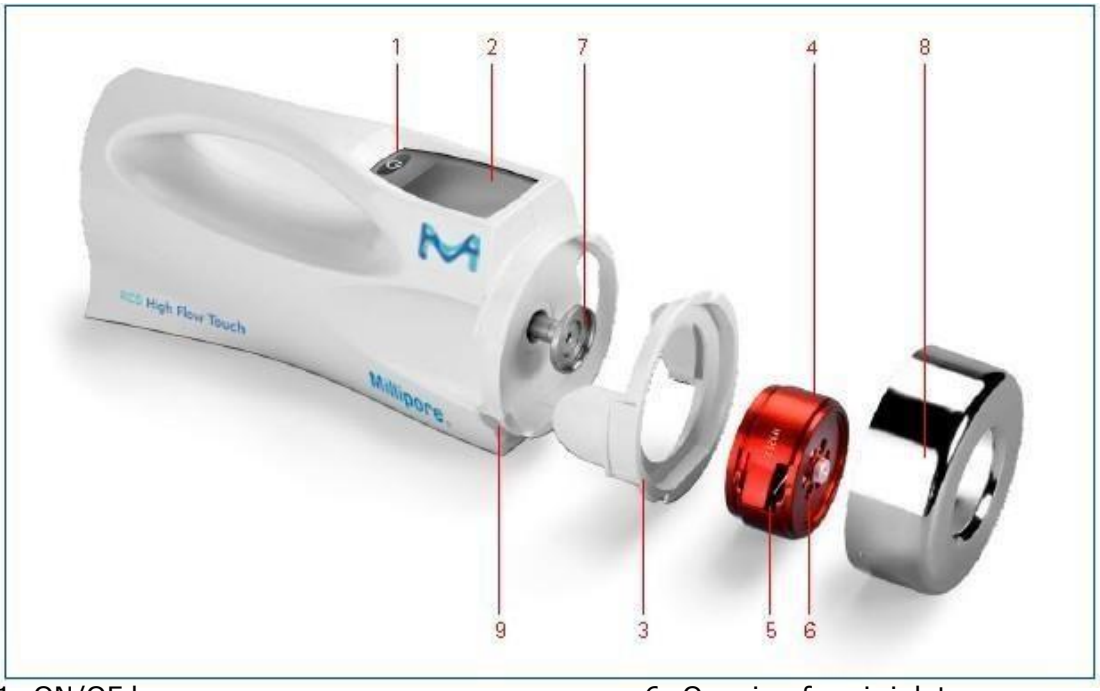
- Definition and selection of sampling volumes
- Definition and activation of a delay time
- Definition and activation of interval sampling / continuous sampling
- Selection of time and language
- Activation of QA Level Management
- Selection of a rotor, monitoring the expiration of rotor calibration (calibration reminder), and calibration data management of up to ten rotors
- RCS® Management Software (included) for user defined sampling options
- Memory function for warnings and error logs
- Automated shut down function

The RCS® High Flow Touch can be used in vertical or horizontal positions. For sampling in areas difficult to access, the instrument can be attached to a tripod using a standard thread at the bottom.

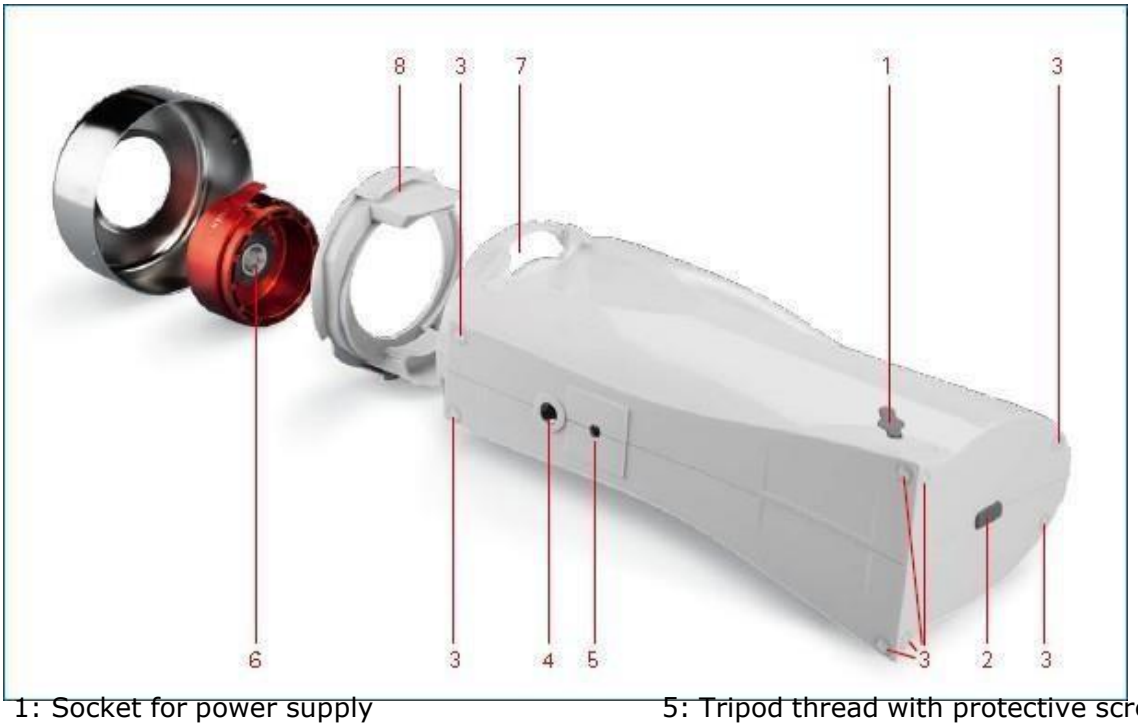
NOTE

1.1.1.1 A safe installation must be ensured prior to sampling. Do not operate the instrument while holding it in the hand. Protect the instrument against strong vibration during sampling.

2.3 Main Components of the RCS® High Flow Touch Microbial Air Sampler



1: ON/OF key
2: High resulution colour touchscreen
3: Detachable air direction ring
4: Rotor
5: Guide for positioning the agar strip
6: Opening for air inlet
7: Magnetic coupling flange
8: Protection cap
9: Bayonet lock for protection cap



1: Socket for power supply
2: Socket for docking station
3: Housing feet
4: Serial RS232 interface with protection cap
5: Tripod thread with protective screw
6: Magnetic coupling
7: Guide for air direction ring
8: Air direction cylinder

2.4 Technical Data and Specifications

Collection principle	Centrifugal impaction according to Reuter (Reuter Centrifugal Sampler, RCS®)
Operation	Portable device with color touchscreen. Battery operation with integrated Lithiumion battery
Range of measurement	1-1999 L (recommended: 10-1500 L)
Flow rate	100 L/min (1000 L in 10 min)
Instrument deviation	± 5%
Sample volume	7 pre-set sample volumes: 10, 20, 50, 100, 200, 500 and 1000 L 3 user defined sample volumes from 1 to 1999 L
Rotor speed	8200 rpm
Tolerable axial force on rotor shaft	30 Newton
Operating conditions	Refer to the safety instruction "RCS – High Flow Touch Microbial Air Sampler addendum" delivered with the instrument.
Automatic power off	Within 8 minutes after the last action.
Material	Housing: Lexan polycarbonate (PC); Sampling head (autoclave-able): Stainless steel/anodized aluminum/ APEC polycarbonate
Interface	Serial RS232 interface, USB adapter, standard tripod thread
Calibration	contact your local technical service at SigmaAldrich.com/techservice
User defined functions	• Individual sample volumes • Delay time • Interval sampling (RCS® Management Software) • QA Level management (RCS® Management Software) • Language, local time • Date (RCS® Management Software) • Rotor selection and rotor management

2.5 Electrical Supply

The RCS® High Flow Touch Microbial Air Sampler is equipped with an integrated Lithium-ion battery to allow for flexible operation independent from mains.
Power Supply and a power cord are contained in the RCS® High Flow Touch supply kit. Optionally, a docking station (Cat. No. 1.44256.0001) is available allowing for convenient recharging after each use. Recharging the battery can be performed at any time independent from the charging status.

NOTES

1.1.1.2 Upon delivery the integrated battery of the RCS® High Flow Touch Microbial Air Sampler may be partially charged. It is recommended to fully charge the battery prior to first use.

1.1.1.3 Throughout the first charging cycles the total capacity of the battery may slightly increase.

1.1.1.4 Charging of the battery with power supply or docking station can be performed at any time. It is recommended to avoid complete discharging of the battery on a regular basis.

1.1.1.5 The minimal remaining battery capacity to start the air sampling is set to two measurements as per selected volume. This is a safety feature.

1.1.1.6 Dependent on age and the frequency of usage the total battery capacity will be reduced. This is a technical feature of Lithium-ion batteries. It is recommended to perform at least an annual diagnosis of the total battery capacity.

1.1.1.7 It is recommended to cover the electrical sockets with the corresponding protection caps upon battery driven usage, or cleaning cycles.

2.6 Ports and Data Transfer

The RCS® High Flow Touch Microbial Air Sampler is equipped with a standard RS232 interface for data transfer between the instrument and a personal computer (PC). If the PC is not equipped with a serial interface the use of a suitable USB adapter is possible. Both the serial RS232 Cable and the USB adapter are supplied with the instrument.

2.6.1 RS232 Interface

The RS232 interface is located at the bottom of the device and is secured with a protection cap in order to prevent fluid entry. Using the serial RS232 cable, the RCS® High Flow Touch Microbial Air Sampler can be connected to a PC. This allows for data transfer and use of the RCS® Management Software:

1. Install the RCS® Management Software on the PC.
2. Remove the protection cap covering the serial interface of the device.
3. Connect the RCS® High Flow Touch Microbial Air Sampler with the PC by using the serial RS232 cable.
4. Start the RCS® Management Software after the RCS® High Flow Touch Air Sampler is connected with the PC and is switched on.

NOTES

1.1.1.8 The RS232 interface is covered with a protection cap to prevent exposure to fluids and dust.

1.1.1.9 It is recommended to remove the RS232 protection cap only when using the RS232 interface.

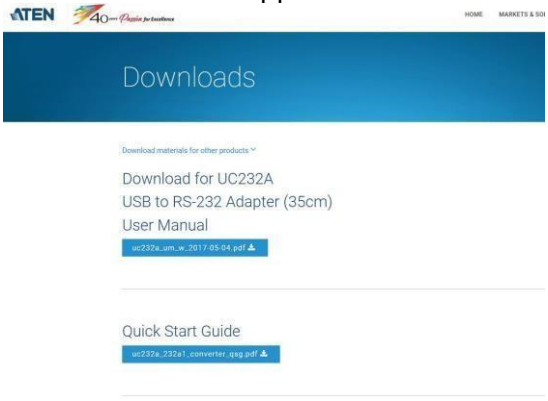
2.6.2 Installation of the USB Adapter

An USB adapter enables a connection between the RCS® High Flow Touch instrument and a PC by using the USB interface of the PC. The USB adapter is supplied with the instrument.

2. TO DOWNLOAD THE REQUIRED DRIVER

- Go to ATEN website => https://www.aten.com
- In the search bar of the website: put USB adaptor reference which is UC232A

- Click on "Support and Download" button



- Many downloads are available, so you must scroll down to this line.

Windows XP, Windows Vista, Windows 7, Windows 8, Windows 8.1, Windows 10, Windows 2012 R2, Windows 2016, Windows 2008 R2	32 bits / 64 bits	v1.0.084	2018-05-23	uc232a_windows_setup_v1.0.084.zip

Now click on the zip file to download it.

1. Connect the USB adapter cable with the USB port of the PC. The new hardware is recognized by the Windows software, the previously installed drivers are allocated, and the new hardware is ready for operation.
2. Connect the serial RS232 cable with the RS232 port of the RCS® High Flow Touch Microbial Air Sampler and then with the USB adapter at the PC.
3. Start the RCS® Management Software after the RCS® High Flow Touch Microbial Air Sampler is connected with the PC and switched on.

2.6.3. RCS® Management Software

The RCS® Management Software is supplied with the instrument. It is used to define or change the user settings by using a PC (see below). The modified data is then transferred to the RCS® High Flow Touch instrument by using the serial RS232 interface (see chapter 2.6.1):
1 Interval Sampling: Defines sample collection cycles consisting of the sampling volume, the number of cycles, and the total time of the collection procedure. The RCS® Management Software calculates the parameters for the interval sampling automatically.
2 Quality Assurance (QA) Level Management: Allows locking of certain functions for the operator. Using the functions <manual change of the calibration factor > (QA Level 2), the <change of sampling volumes > (QA Level 3), and the <selection of rotor > (QA Level 4) by the can prohibited.
3 Time/Date: The date can only be changed by using the RCS® Management Software. This is a security function.

NOTE

2.1.1.1 For a detailed description of the RCS® Management Software please refer to the corresponding User Guide.

2.7 Tripod Connection

The RCS® High Flow Touch Microbial Air Sampler is equipped with a standard thread for attachment of a tripod or a table-top tripod at the bottom of the instrument. The tripod thread is protected against fluid entry with a protective screw. Tripods are used for the following applications:

- The table-top tripod allows for a safe stand on uneven surfaces during horizontal installations
- The table-top tripod will minimize vibrations on very smooth surfaces during horizontal installations
- The tripod allows for sampling procedures in heights of up to three meters
- Prior to attachment of a tripod or table-top tripod the protective screw at the bottom of the instrument must be removed by using a Philips screwdriver

NOTE

2.1.1.2 It is recommended to always protect the tripod thread with the protective screw when no tripod is connected. It is recommended to protect the tripod thread with the protective screw during disinfection or cleaning procedures to avoid fluid entry.

2.8 Optional Accessories

The following optional accessories are available for the RCS® High Flow Touch Microbial Air Sampler:

ITEM	CAT. NO.
Docking Station	1.44256.0001
Compressed Gas Adapter Touch	1.44257.0001
Nozzle Set	1.44235.0001
Tripod	1.44209.0001
Table-top Tripod	1.44210.0001
Rotor	1.44196.0001
Validation protocol	RCHFA4VP1
Validation protocol	RCHFLTVP1
Protection Cap Additional protection cap (must be calibrated with theinstrument)	1.44225.0001
Air Direction Ring	1.44198.0001
Power Supply	1.44145.0001
Serial RS232 Cable	1.44207.0001
USB Adapter	1.44152.0001
Carrying Case	1.44150.0001

AGAR STRIP TYPE	CAT. NO.	DESCRIPTION
TC	1442530050	Tryptic Soy Agar; for determination of total counts
TSM	1442400050	Modified Tryptic Soy Agar with neutralizers for disinfectants; for determination of total counts including fastidious and sublethal damaged airborne microorganisms
TC-γ	1442260040	Double-wrapped, γ-irradiated Tryptic Soy Agar; for determination of total count in aseptic environments
TCI- γ	1442280040	Double-wrapped, γ-irradiated Tryptic Soy Agar with neutralizers; for determination of total counts in asepticenvironments with peroxide containing air
LAC-γ	1441080040	Double-wrapped, γ-irradiated Tryptic Soy Agar with β-Lactamase I & II for inactivation of a broad range of β-Lactam-antibiotics
YM	1442420050	Rose Bengal Agar with streptomycin and chloramphenicol;for determination of yeast and molds
SDX	1442430050	Sabouraud Dextrose Agar with modified Pharmacopeiaformulation; for determination of yeast and molds
SDX-γ	1442440040	Double-wrapped, γ-irradiated Sabouraud Dextrose Agar with modified Pharmacopeia formulation; for determinationof yeast and molds in aseptic environments

DG-18	1442450025	Dichloran Glycerin Agar; for determination of xerophilicyeast and molds
Cover Slides	1441110100	For sealing the agar strips during incubation
Blank Strip Kit	1441070050	Sterile and empty foil, for production of agar strips withown formulations

3 Installation of the Instrument

3.1 Scope of Supply/Checklist

The RCS® High Flow Touch Microbial Air Sampler is delivered in a metal carrying case containing the items listed below. Please use this list to verify that the scope of supply is complete. When used in controlled areas the instrument might be subjected to Installation and Operation Qualifications (IQ/OQ, please contact our services).

NOTES

2.1.1.3 Operation guides, RCS® Management Software, and other documentation are located behind the top foam layer inside the carrying case.

2.1.1.4 Verify the calibration certificate for all delivered rotors.

2.1.1.5 Upon transport remove the rotor from the instrument and place it into the corresponding compartment of the carrying case.

2.1.1.6 The RCS® High Flow Touch Microbial Air Sampler should be used only with calibrated rotors containing a serial number starting with a "H".

3. RCS® HIGH FLOW TOUCH ARTICLE NO. 1.44194.0001:

- RCS® High Flow Touch
- Rotor
- Protection Cap
- RCS® Management Software with User Guide (USB Key)
- User Guide (USB Key)
- Safety instructions (USB Key)
- Quick Start Guide
- Power Supply and Power Cord
- Serial RS232 Interface Cable
- USB adapter
- Calibration Certificate for Rotor(s)
- Carrying Case

3.2 Power Supply and Charging

The RCS® High Flow Touch Microbial Air Sampler is equipped with an integrated Lithium-ion battery. Recharging of the battery is performed with the supplied power supply (1441450001) or an optional Docking Station (Cat. No. 1442560001). For a new instrument the total capacity of the battery corresponds to more than 30 x 1000 L measurements.

With lower sampling volumes the amount of potential measurements increases accordingly. The battery status is indicated by the RCS® High Flow Touch software:

Upper: status bar of the main menu. The number displayed is dependent on the selected sampling volume. The number >30 indicates that more than 30 measurements are feasible.
Middle: Status bar of the main menu with connected power supply or docking station. As of 90% recharging the charging status is indicated (here: 93%).

Lower: System information (menu path: Setting - Option - System): The upper symbol indicates the total capacity of the battery. This is independent of the actual battery charging status. The lower symbol indicates the actual charging status and the number of remaining measurements (right) dependent on the selected sample volume (left).

3.2.2 Charging with the Power Supply

Connect the power supply with the outlet. Remove the protection cap that covers the power supply socket at the left-hand side of the instrument and connect the power supply with the RCS® High Flow Touch Microbial Air Sampler.

3.2.3 Charging with the Docking Station

Connect the power supply with the outlet. Then, connect the docking station with the power supply.

The electrical supply is indicated by the green LED signal. Remove the protection cap that covers the docking station socket at the bottom of the RCS® High Flow Touch Microbial Air Sampler. Place the instrument into the docking station.

NOTES

3.1.1.1 The battery of the instrument might be partially charged. It is recommended to fully charge the battery prior to first use.

3.1.1.2 Throughout the first charging cycles the total capacity of the battery may slightly increase.

3.1.1.3 Charging of the battery can be performed at any time. If the battery is completely discharged a full loading cycle may take 2-3 hours.

3.1.1.4 Connected to the power supply the instrument can perform any number of measurements.

3.1.1.5 The minimal remaining battery capacity to start the air sampling is set to two measurements as per selected volume. This is a safety feature.

3.3 Handling of the Agar Strip and the Rotor

To insert the agar strip into the rotor first remove the protection cap from the sampling head by turning it counterclockwise. Then, pull the rotor from the magnetic flange.

1. Open the protective foil that is covering the agar strip for approximately 4 cm (Figure 1).
2. Carefully remove the agar strip by holding it at the sides (Figure 2). Avoid touching the agar surface.
3. Insert the agar strip into the rotor with the agar surface facing to the inside (Figure 3). Take care to fully insert the agar strip.

4

5

1. Position the rotor back to the magnetic flange after the agar strip is completely inserted (Figure 4).
2. Mount the protection cap on top of the rotor by turning it clockwise (Figure 5).

Switch the Instrument ON and Proceed with Air Sampling

Switch the instrument ON by using the ON/OFF button below the touch screen. Then, select an appropriate sampling volume. Start the air sampling by touching the start button. A detailed description for programming and operation is outlined in chapter 4.

Removal of the Agar Strip

- Unscrew the protection cap and remove the rotor from the magnetic flange.
- To remove the agar strip, pull out by the strip holder. Place the agar strip back into the protective packaging with the agar surface facing downwards (the outer area facing towards the protective foil).
- Seal the protective packaging by using a cover slide provided with the agar strips to avoid drying of the agar during incubation.

NOTE

3.1.1.6 It is recommended to label the agar strips with most important parameters to avoid mistakes during analysis.

Incubation and Analysis

Counting of colonies is performed after an appropriate incubation period with the agar strip still placed within its protective packaging. The number of Colony Forming Units (CFU) on the entire agar strip is analyzed in relation to the air volume sampled (in liters). The calculation of CFU per cubic meter (m^3) is performed according to the following formula:

$$CFU/m^3 = \frac{\text{CFU per agar strip}}{\text{Selected sample volume (liters)}} \times 1000 \text{ (liters)}$$

NOTE

3.1.1.7 For incubation conditions please follow the general guidelines for the respective bacteria and molds or refer to the data sheet delivered with the product.

4 Operation of the Instrument

4.1 General Information

NOTES

3.1.1.8 Prior to operation of the instrument carefully read this User Guide and the safety instructions.

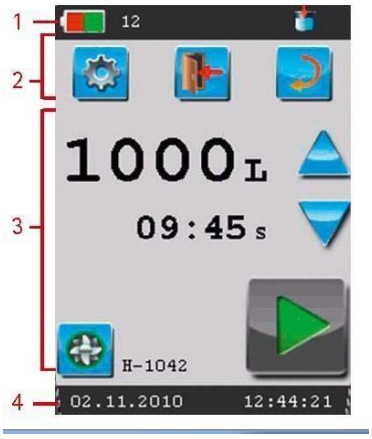
3.1.1.9 Prior to first use of the RCS® High Flow Touch Microbial Air Sampler it is recommended to fully charge the integrated battery (see chapter 3.2).

3.1.1.10 The instrument is non-sterile upon delivery. If the instrument is used in aseptic environments, please follow the recommendations for sterilization/ decontamination (see chapter 5.2).

3.1.1.11 For delivery the RCS® High Flow Touch Microbial Air Sampler is set to a "sleep" mode. With the first activation of the software the expiration for the rotor calibration is set to 365 days (one year)

4.2 Structure of the Main Menu

When switching on the RCS® High Flow Touch Microbial Air Sampler the initialization is indicated by the Vibrant M. Then, the Main Menu is displayed. The Main Menu allows for the selection of an appropriate air sample volume and the start of the air sampling procedure. The Main Menu also allows for visual control of the battery status and user defined settings for air sampling. The Main Menu is subdivided into three information areas and a navigation area (from top to bottom):

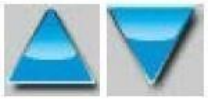


1. Status bar: To the left, the battery status and the number of remaining measurements as per selected volume is displayed. To the right, the active menu is indicated by the corresponding icon.
2. Navigation area: From left to right with the icons for "Setting Menu", "back to main menu/abort", and "one step back".
3. Selection of the sample volume by using the arrows.
4. Date (left, dd.mm.yyyy) and Time (right).

4.3 Overview on Menus and Icons Displayed

The following table summarizes the main software menus and icons displayed by the RCS® High Flow Touch software. The operation of the software menus is explained in detail in the following chapters.

Menu/Icon	Description
	Main Menu • Upper: Selected sampling volume and sampling time. • Side: Arrows for changing the sampling volume. • Lower left: Selected rotor. For changing the rotor touch the icon to go to the Rotor Menu. • Lower right: Start button to start the air sampling procedure.
	If the calibration for the selected rotor is expired the rotor symbol is displayed in red.
	Setting Menu: Contains the submenus "Individual Volume", "Delay Time", "Interval Sampling", "Option", and "QA Level".
	Individual Volume: Access to three additional positions for the definition of user defined sampling volumes.
	Delay Time (displayed in the Main Menu upon activation): Programming of a delayed sampling start from 1 min to 2 h and activation.
	Interval Sampling (Requires the RCS® Management Software, displayed in the Main Menu upon activation): Control of selected parameters and activation.
	Menu Option: Contains the submenus "System", "Date/Time", "Language", "Rotor", "Error Log List" and "Service Area".

	QA Level Management
	System: Displays the serial number of the device, version numbers of the software (VISU) and firmware, and the battery capacity data.
	Date/Time: Adjustment of local time and the time format. The date can only be changed by using the RCS® Management Software.
	Language: Language selection by touching the button until the respective flag is displayed.
	Menu Rotor: Selection of a rotor, calibration expiration information, manual change of the calibration factor.
	Calibration Factor: Changing the calibration factor for an expired rotor.
	Error Log List: Displays errors occurred during operation.
	Back to Main Menu/Abort.
	One step back.
	Start air sampling.
	Stop air sampling.
	Save data.
	"Scrolling" within a selection menu, for example, sample volume selection.
	Activation/Deactivation of an option, for example, the Interval Sampling.

4.4 Switching the Instrument ON

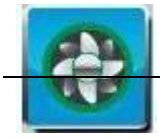
Switch on the Instrument by pressing the ON/OFF button below the touchscreen. The initialization is indicated by the Vibrant M. The initialization is completed when the Main Menu is displayed.

NOTE

3.1.1.12 For safety reasons the instrument can be only operated with the protection cap installed.

4.5 Rotor Selection

The Rotor Menu can be selected directly from the Main Menu or from the Option Menu. For each selected rotor the serial number and the expiration
date of the calibration is displayed. The rotor is selected or changed by using the arrows.



The rotor icon gives access to the Rotor Menu. Here, the rotors that have been calibrated with the device are displayed and can be selected by using the arrows.

A red rotor icon indicates that the calibration of the rotor has expired.

	Selection of a rotor from the list of calibrated rotors.
	Save selected rotor.
	Go to Menu Calibration Factor.

4.6 Sample Volume Selection

The instrument is offering ten positions for sample volumes. Factory settings reserve the first seven positions for the volumes 10, 20, 50, 100, 200, 500 and 1000 liters. Three addional positions can be user defined with sampling volumes from 1 to 1999 liters.

After the instrument has been switched on the previous sampling volume is displayed. Another sampling volume can be selected by using the arrows.

For higher sample volume values use the icon. 

For lower sample volumes use the icon. 

The appropriate sample volume is dependent on the number of suspected microorganisms. It is recommended to select a sample volume that yield a statistically representative number of colony forming units (CFU) on the agar strip. The number of expected colonies corresponds to a sampling volume of 1000 L. The table below indicates the expected CFU as per sample volume:

Expected total counts in CFU/m³ of ambient air	Sample volume RCS® High Flow Touch	Number of CFU per agar strip	Factor (multiply with counted CFU to receive CFU/m³
0-10	1000	0-10	1
10-200	500	5-100	2
200 to 500	200	40-100	5
500 to 1.000	100	50-100	10
1.000 to 2.500	50	50-125	20
2.500 to 5.000	20	50-100	50
5.000 to 10.000	10	50-100	100

NOTE

3.1.1.13 If the expected number of CFU is unknown it is recommended to select a higher sample volume to avoid false-negative results.

4.7. Start the Air Sampling

After the appropriate sampling volume has been selected the air sampling process is started by touching the icon  . During air sampling the remaining sample volume and the remaining sampling time is displayed. Optionally, the remaining time can be switched to the large display section by a simple touch. Completion of the air sampling is indicated by "0 L" and an acoustic signal. When touching the screen, the acoustic signal is stopped
and the last sampling volume is displayed.

NOTE

3.1.1.14 If necessary, the air sampling process can be interrupted at any time by touching the Stop icon  . Then, the sampling process can be continued by touching the  icon or terminated by touching the icon  .

4.8 Switching the Instrument OFF

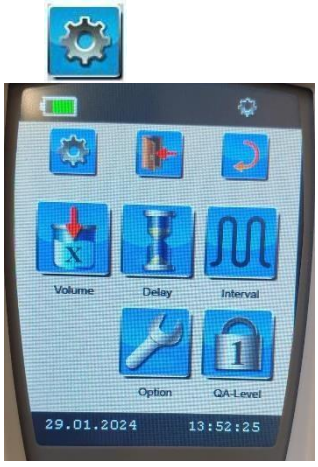
The RCS® High Flow Touch Microbial Air Sampler is switched OFF by pressing the ON/OFF button for 2 seconds. The termination of the software is indicated by the Logo "RCS® High Flow Touch".

The instrument is also equipped with an automated powering off function. This function is activated within eight minutes after completion of the last air sampling or the last software command.

NOTE

3.1.1.15 If the instrument has switched itself off automatically it is recommended to verify the correct completion of the air sampling process before the agar strip is removed. Therefore, the instrument is switched on. If no error occurred, the last sampling volume is displayed.

4.9 Additional Functions (Menu Setting)



The Setting icon of the Main Menu provides access to the following user defined functions:

- **Individual Volume** Access to three additional sample volume positions.
- **Delay Time** Access to program a delayed sampling start.
- **Interval Sampling** Access to the parameters of an interval sampling Procedure and activation of the interval sampling. The parameters are programmed by using the RCS® Management Software.
- **Option** Access to various system information menus and user defined instrument settings.
- **QA Level** Access to the authorized QA Level. The QA Level is programmed by using the RCS® Management Software.

Touching the Individual Volume icon from the Menu Setting provides access to the Menu Individual Volume. This menu allows the definition of three additional sample volumes. By touching one of the icons 8-10 the respective position is activated as indicated by the dark background. The value can be adjusted by using the arrows .

Save the new value and return to the main screen. The new sample volume can be selected from the Main Menu.

One step back (Setting Menu).

Go back to the Main Menu (Abort).

4.9.1 Delay Time

Touching the Delay Time icon from the Menu Setting provides access to the Menu Delay Time for the definition of a delayed sampling start.
A delay time is programmed with the format HH:MM. First, the position is activated. Then, hours and minutes can be adjusted by using the arrows .

A delay time between 1 minute and 2 hours can be selected.
A delay time is programmed with the format HH:MM:SS. First, the position is activated. Then, hours and minutes are adjusted by using the arrows. A delay time between 1 minute and 2 hours can be selected.

Activation of a delayed sampling start.

Save the new value and return to the Main Menu. The icon indicating the delay time and the programmed value is then displayed in the Main Menu.

One step back (Setting Menu).

Go back to the Main Menu (Abort).

NOTE

3.1.1.16 The delay time needs to be activated by setting the icon to ON (magenta). Activation is indicated by the Delay Time icon in the Main Menu. Upon starting the air sampling, the icon switches from blue to magenta indicating the start of air sampling.

4.9.2 Interval Sampling

Touching the Interval Sampling  icon from the Menu Setting provides access to the Menu Interval Sampling for verification of parameters and the activation of the interval sampling procedure. The parameters for the interval sampling procedure are programmed with the RCS® Management Software.

In this example the following interval sampling procedure is displayed:
-- Sample volume of 100 L
-- 8 intervals
-- Time period of 10 minutes

For activation of the interval sampling mode the ON/OFF  icon is set to ON (magenta). The icon for Interval Sampling is displayed in the Main Menu.

 Activation of interval sampling.

 Saving new data is not allowed.

 One step back (Setting Menu).

 Go back to the Main Menu (Abort).

NOTE

3.1.1.17 The interval sampling mode is programmed with the RCS® Management Software and transferred via the serial RS232 interface. If no interval sampling data have been transferred activation of this mode is not possible.

4.9.3 QA Level

Touching QA Level  icon from the Menu Setting leads to the QA Level menu. The number displayed in the lock indicates the QA Level that has been programmed with the RCS® Management Software. With different QA Levels the access to the function's calibration factor, rotor selection and volume selection can be blocked.

	Level 1: Factory setting, access to all functions.	
	Level 2: Changing the calibration factor is blocked.	
	Level 3: In addition, change of the sampling volume is blocked.	
	Level 4: In addition, change of the rotor is blocked.	

4.9.4 Options

Touching the Option icon from Menu Setting provides access to the Menu Option. Here, the following menus are available:

- System information
- Setting the time and the time format
- Selection of the language
- Rotor Menu (rotor list, calibration data, and calibration factor)
- Error Log List
- Service Area

4.9.5. System Information

Touching the  Option icon followed by the  System icon provides access to the Menu System Information. Here, the following information is displayed (upper to lower):

- Serial number of the RCS® High Flow Touch Microbial Air Sampler
- Software version (VISU)
- Firmware version
- Total battery capacity
- Actual battery charging status
- Number of remaining measurements (right) as per selected sampling volume (left)

NOTES

3.1.1.18 The instrument is supplied with a partially charged battery. Prior to first use it is recommended to fully charge the battery.

3.1.1.19 Throughout the first charging cycles the total capacity of the battery may slightly increase.

4.9.6 Time Selection

Touching the  Option icon followed by the  Time icon provides access to the Menu Date/Time. The time is displayed in the format hh:mm:ss. For adjustment the respective area is touched for activation, then changed by using the arrows  The format of the time can be changed between a 12 hour format and a 24 hour format. Therefore, the area 12 h/24 h is touched and the new setting is saved. The changed time format is displayed in the lower status bar. The date can only be changed with the RCS® Management Software. The new date is then transferred to the instrument via the RS232 interface.

The date can only be changed with the RCS® Management Software. The new date is then transferred to the instrument via the RS232 interface.

 Save new data and return to the Main Menu.

 One step back (Option Menu).

 Go back to the Main Menu (Abort).

NOTE

3.1.1.20 It is recommended to change date and time with the RCS® Management Software and transfer the new data to the instrument via the RS232 interface.

4.9.7 Language Selection

Touching the Option icon followed by the Language icon provides access to the Menu Language. By selecting the appropriate country flag the language displayed throughout the user interface is selected. There is a choice between the following languages: German, English (UK/US), French, Italian, Spanish, Japanese, Dutch, Russian, and Chinese.

4.9.8 Rotor

Touching the Option icon followed by the Rotor icon provides access to the Menu Rotor. Here, the following functions can be selected:

- Selection of a rotor from the Menu by using the arrows.
- Verification of the calibration expiration for a given rotor.
- Manual correction of the calibration factor for a given rotor.

Save the selected rotor and return to the Main Menu.

One step back (Option Menu).

Go back to the Main Menu (Abort).

4.9.9 Error Log List

Touching the Option icon followed by the Error Log List icon provides access to the Error Log List.
Here, all error codes are listed with date and time information. For description of the error codes please refer to chapter 6.

One step back (Option Menu).

Go back to the Main Menu (Abort).

5 Service and Maintenance

5.1 Reset

If errors in the power supply or another external condition cause a software freeze, the RCS® High Flow Touch Microbial Air Sampler recognizes this event automatically and performs an automated reset. During the automated reset the instrument powers off. It can be restarted by using the ON/OFF button. The initialization is indicated by the Vibrant M. In the unlikely event that the instrument is not capable to perform an automated reset a manual reset can be performed. Therefore, the ON/OFF button is pressed and hold for approximately eight seconds. The instrument switches off and then, switches on again. The initialization is indicated by the Vibrant M.

NOTE

3.1.1.21 For more information on the reset of certain functions or the reconstitution of the factory settings please contact Customer Service.

5.2 Sterilization and Disinfection

The housing of the RCS® High Flow Touch Microbial Air Sampler is made from a very resistant polycarbonate (Lexan polycarbonate). It can be disinfected by wiping or spraying with commercially available disinfectants that are compatible with polycarbonates (pH 5-8). For further material compatibility information please contact the supplier of your specific disinfectant agent.

For protection of the motor and the electric circuits please avoid extremely wet conditions (i.e. by dipping the instrument into fluids or by over-use of sprays).

The Rotor, the Protection Cap and the Air Direction Ring can be autoclaved at 121 °C for 20 minutes.

Avoid dry heat. The instrument itself cannot be autoclaved.

NOTE

3.1.1.22 For cleaning routines unplug the RCS® High Flow Touch Microbial Air Sampler and any electric accessory hardware from electrical supply.

5.3 Cleaning of the Rotor

It is recommended to occasionally clean the rotor thoroughly. For this, cleaning of the complete rotor in an ultrasonic bath or treatment with commercially available disinfectant followed by rinsing with water can be applied. Alternatively, the rotor can be taken apart by unscrewing the knurled nut. Following, the parts can be cleaned in a water bath or by using brush tools. Since the rotor is a precision part that influences the air flow characteristics of the device all components must be handled with special care. If more than one rotor is taken apart special care must be taken to not mix up parts. Please note that the rotor cover and the rotor cylinder are labeled with numbers. For corresponding parts these numbers must be identical.

NOTE

3.1.1.23 After the rotor has been taken apart and reassembled a calibration of the rotor is recommended.

3.1.1.24 After the rotor has been cleaned, it should be well dried.

5.4 Exchange of the Air Direction Ring

The Air Direction Ring can be removed from the instrument for cleaning purposes or for exchange after being damaged. The Air Direction Ring is made from resistant polycarbonate (APEC polycarbonate) and can be autoclaved at 121 °C for 20 minutes. Avoid dry heat. For removal the Air Direction Ring is carefully pulled upwards by pushing at the sides of air release until the ring is removed from its guide. Carefully take off the Air Direction Ring.

5.5 Lithium-ion Battery

The RCS® High Flow Touch Microbial Air Sampler is equipped with an integrated Lithium-ion battery. The total capacity of the battery is slowly reduced over a longer period of time. Thus, it is recommended to check the battery capacity periodically. The battery should be exchanged by a certified technician if the capacity is not enough for the daily measurements. Contact your sales representative or technical service for more information about our services available.

5.6 Calibration

5.6.1 Calibration of the Touchscreen

A calibration of the touchscreen is recommended if the software fails to respond to a clear touch with appropriate pressure, or if the touch area seems to move sideward. The Menu Service Area provides access to the calibration of the touchscreen. By touching the Calibration icon the touchscreen turns black and a white cross appears in the upper left corner.

Press the cross with a narrow touch instrument (stylus). Then, repeat the procedure for all four corners of the touch area by following the appearance of the white cross. After the calibration of the touchscreen is finalized the instrument automatically returns to the Menu Service Area.

5.6.2 Calibration of the Rotor

The RCS® High Flow Touch Microbial Air Sampler is delivered with a calibrated rotor. Optionally, an instrument can be calibrated with more than one rotor. For every calibrated rotor a calibration certificate is provided. After first use of the instrument each rotor must be calibrated at least once a year. For control of servicing intervals, the calibration expiration date for each rotor is stored in the memory of the instrument. Generally, the calibration expiration date of a rotor is set at 365 days (1 year). Send instrument and rotor for annual calibration service to your local service provider.
For annual rotor calibration please contact your local sales representative for more information about our calibration service and service plans.

NOTE

3.1.1.25 Rotor and instrument are required for a calibration.

3.1.1.26 A calibration should be performed at least annually.

3.1.1.27 A calibration is performed after tearing apart the rotor apart for cleaning (see chapter 5.3).

3.1.1.28 An expired rotor is indicated by the red rotor symbol.

3.1.1.29 If an expired rotor is used with QA Level 2-4 an error message is displayed.

3.1.1.30 Measurements with an expired rotor is possible but not recommended.

3.1.1.31 7 Spare Parts/Services

6 Description of Error Codes

No.	Code / Icon	Description	Action
		WARNING!	Refer to the user guide !
1	 21	Protection cap is missing	Mount the protection cap
2	 22	Rotor is blocked	Verify the correct assembly of the rotor and the protection cap. Check if the agar strip is inserted correctly
3	 23	Battery is empty	Recharge the battery
4	 32	Rotor calibration is expired	Calibration of the rotor is required
5	 01	Memory error: • Volume table/Delay Time	Reprogram the individual sample volume/delay time
6	 02	Memory error: • Calibration Factor (Rotor table)	Calibration of the rotor is required (Technical Service)
7	 03	Memory error: • Rotor status (Rotor table)	Calibration of the rotor is required (Technical Service)
8	 04	Memory error: • Expiry date (Rotor table)	Calibration of the rotor is required (Technical Service)
9	 05	Memory error: • QA Level (Rotor table)	Reprogram the QA-Level
10	 06	Possible hardware error: • Timing not recognized correctly after switching the device on	Adjust the time. If the error maintains or continues repair of the instrument is required. Please contact our serivce team.
11	 07	Memory error: • Time conflict Interval Sampling parameter (Manual Rotor Calibration only)	Reprogram the Interval Sampling parameters
12	 08	Memory error: • Calculation of Interval Sampling parameters	Reprogram the Interval Sampling parameters
13	 09	Writing error	Repair of the instrument is required. Please contact our service team.
14	 10	Reading error	Repair of the instrument is required. Please contact our service team.

7 RCS® Compressed Gas Adapter Touch (CGA)

The RCS® Compressed Gas Adapter Touch (CGA; Cat. No. 1442570001) allows for a simple yet effective measurement of the microbial quality of compressed air and gas in a pressure range of 0.1 bar to 7 bar. The adapter is suitable for non-flammable and non-toxic gases.

7.1 Functional Principle

The RCS® Compressed Gas Adapter Touch consists of a diffusor, a reduction nozzle, and a tube connection that allows for the connection of a compressed gas pipeline to the adapter.
The tube connector of the RCS® Compressed Gas Adapter has a thread size of R1/4 and is designed as a universal connection. The tube connector can be replaced easily by a connector of a different size, or a quick coupling connection. It is important that the connector is always securely attached to the reduction nozzle – an important component of the RCS® Compressed Gas Adapter.

The gas to be analyzed enters the RCS® Compressed Gas Adapter through the tube connection. Thereby, the velocity of the volume flow is restricted by the reduction nozzle. The flow cross-section of the air stream is expanded within the diffusor, and the flow velocity is continuously reduced. Following, the gas is used by the attached RCS® Microbial Air Sampler almost pressure-free. An excess gas rate throughout the measurement allows for a constant flow rate during sampling. The excess amount of gas is released through exhaust channels and directed over the protection cap of the RCS® High Flow Touch Microbial Air Sampler.

7.2 Sterilisation and Decontamination

Sterilization and decontamination measures should be established for the RCS® Compressed Gas Adapter and the reduction nozzles and carried out routinely. The components of the adapter are made of aluminium and stainless steel.

Cleaning and disinfection can be performed by rinsing or spraying with commercially available cleaning and disinfecting agents. The agent should have a neutral pH value (pH: 5–8) to protect the anodized aluminium coating of the diffusor. Please ensure to use cleaning agents compatible with aluminium and stainless steel.

Alternatively, the adapter can be gas-sterilized or autoclaved at 121°C. After sterilization, it is recommended to store the adapter in a sterile container or bag.

7.3 Installation and Sampling

The assembly of all components has to take place in a aseptic environment. It is recommended to sterilize the RCS® Compressed Gas Adapter before use. Prior to microbial sampling of compressed gas, the RCS® High Flow Touch Microbial Air Sampler must be equipped with a rotor containing the agar strip and the protection cap.

The RCS® Compressed Gas Adapter is connected to the pressured gas line. Ensure a tight and close fit between the adapter and pressured gas line. If necessary, disinfect the connecting parts.

For assembly of the RCS® Compressed Gas Adapter with the RCS® High Flow Touch, place the air sampler in a horizontal position on a stable surface. Gently push the diffuser of the adapter over the protection cap of the sampling head of the RCS® Microbial Air Sampler allowing it to be secured in this position. The longer legs of the stand need to face downwards. Next, open the pressure valve and make sure that the pressure does not exceed the pressure range of the reduction nozzle.

As the compressed air begins to flow through the adapter, it will produce a marked hissing noise that is derived from the expansion cylinder. The gas should escape for approximately 1 minute before the RCS® High Flow Touch is started. After completion of air sampling, close the valve of the compressed line and remove the RCS® Microbial Air Sampler from the adapter.

If required, transfer the RCS® High Flow Touch or the rotor containing the agar strip into a sterile container in order to protect the agar strip from secondary contaminations. Remove the agar strip from the rotor and place it back into the original wrapper. Label the wrapper and proceed with the incubation of the agar strip. If multiple measurements are performed for the same compressed gas outlet, do not close the compressed air valve during replacement of agar strip or rotor.

IMPORTANT NOTES

3.1.1.32 The diffusor of the RCS® Compressed Gas Adapter contains longer legs at one side and short legs on the other side.

3.1.1.33 For installations with the RCS® High Flow Touch Microbial Air Sampler, the longer legs are facing downwards. For installations with the RCS® High Flow Microbial Air Sampler, the shorter legs are facing downwards.

7.4 Nozzel Set

The Nozzle Set is used in combination with the RCS® Compressed Gas Adapter for microbial monitoring of compressed gases. The set consists of five reduction nozzles that are designed to extend the application range of the RCS® Compressed Gas Adapter to an overpressure of from 0.1 bar to 7.0 bar. In total, there are six nozzles available for the RCS® Compressed Gas Adapter. The 1 bar nozzle is installed upon delivery of the adapter.

For microbial monitoring of compressed gas pipelines, select the appropriate nozzle according to the inlet flow rate of the pressured gas within the gas line.

Overpressure Inlet (bar)	0.1 to 0.2	0.2 to 0.4	0.4 to 0.8	0.8 to 1.2	2.0 to 4.0	5.0 to 7.0
Nozzle	0.15 bar	0.3 bar	0.6 bar	1.0 bar	3.0 bar	6.0 bar

IMPORTANT NOTES

3.1.1.34 Selection of the correct nozzle is mandatory to allow for a flow rate of 100 L/min for the RCS® Microbial Air Sampler. A flow rate lower than 100 L/min may force the RCS® instrument to pull air from the surrounding environment in addition to the air received from the gas line. This may lead to incorrect (false positive) results.

3.1.1.35 If the pressure of the gas line is at the upper or lower limits of a nozzle, please select the nozzle for the lower pressure range. For example, if the inlet overpressure is 0.4 bar use the 0.3 nozzle. This will ensure that the flow rate is maintained, and an excess of gas prevents that air is taken in from the environment.

Install the nozzle according to the following instruction:

1. Obtain 2 small adjustable wrenches, or a jaw wrench WS 14 and a jaw wrench WS 17. (not included in delivery) Place the jaw wrench WS 14 on the nozzle mount and the jaw wrench WS 17 on the barbed hose fitting.
2. Hold the nozzle mount while slightly twisting the jaw wrench on the barbed fitting to remove this piece.Remove the nozzle that is installed inside the cone and replace it with the nozzle chosen with help of the table above. Make sure to install the copper sealing ring on top of the nozzle to ensure a tight fit.
3. Screw the barbed fitting securing the nozzle into place by using the jaw wrenches.

Nozzle Mount

Nozzles Copper Sealing Ring Barbed Fitting

8 Standard Product Warranty

The applicable warranty for the products listed in this publication can be found at Terms and Conditions (sigmaaldrich.com) (within the "Terms and Conditions of Sale" applicable to your purchase transaction).
If a warranty case occurs, customers may contact the life science business of Merck Life Science KGaA, Darmstadt, Germany and/or its affiliates.

9 Technical Service

For more information visit Customer Support (sigmaaldrich.com)

10 Manufacturer

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